DETAILED ACTION

Election/Restrictions

1. This application contains claims 24-37 drawn to an invention nonelected with traverse in the reply filed on 10/20/2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments

2. Applicants' arguments, filed 6/22/2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

3. Applicant's arguments with respect to the rejection under 35 USC 103 have been fully considered but they are not persuasive:

Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amin et al. (WO 99/55706; 1999; IDS 5/2/2006 reference) and either of the following: Harding ("Nocturnal asthma: role of nocturnal gastroesophageal reflux"; 1999; Chronobiology International; 16(5): 641-62) or Carr et al. ("Case Report: Severe non-obstructive sleep disturbance as an initial presentation of gastroesophageal reflux disease"; 1999: International Journal of Pediatric Otorhinolaryngology' 51: 115-120; IDS 5/1/2007reference, Cite No. C).

The rejection is maintained for the reasons of record.

It is noted that applicant relies on three website URL addresses in attempt to provide evidence in support of positions argued. However, the webpage documents have not been made of record. When the Examiner attempted to retrieve the websites referenced, only error messages were received in the web browser. Therefore, these references have not been considered.

Applicant argues that the specification at paragraph 0009 of the published patent application No. 2004/0280944 (i.e., p. 2, lines 20-24 of the instant specification) defines that a patient suffering from silent GERD does not experience heartburn symptoms or other typical reflux symptoms, e.g., regurgitation; rather, the target population of the claimed method includes patients having disrupted or fragmented sleep in response to a reflux event which the patient may or may not recall having had. A review of this passage in the instant specification indicates that the patient "does not experience heartburn symptoms or other typical or traditional reflux symptoms", with only the example of regurgitation given. The specification passage does not specifically exclude asthma. The record indicates that Harding specifically teaches that 24% of those with asthma have "clinically silent" gastroesophageal reflux. This patient subpopulation is clearly contrasted to asthmatics with heartburn or experiencing reflux-associated respiratory symptoms (abstract), i.e., the symptoms referenced in the instant specification passage. Thus the "clinically silent" subpopulation of Harding is taken to be a teaching of patients with "silent GERD", required by the instant claims. As indicated in MPEP 2106 (I) (C):

> USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44

> USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim… claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily…. During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.

In the instant case, the broadest reasonable construction of claim 20 is taken to include patients with asthma that have "clinically silent" gastroesophageal reflux as falling within the scope of patients in need thereof.

Applicant argues that the child reported by Carr unequivocally manifested several typical symptoms of GERD, but was misdiagnosed; that the child's symptoms are typical of GERD; therefore the pediatric patient of the case study discussed by Carr does not fit the target population of the claimed method; i.e., patients who do not experience typical GERD symptoms, e.g., coughing, hoarseness, halitosis, vomiting, etc. It is noted that these symptoms are not specifically excluded from the patient population by the instant specification, and the evidence referenced is not of record. However, even if applicant's point of view is adopted, that the Carr child case report was a child that had a "non-silent" form of GERD, the background clearly indicates that sometimes GERD is "silent", presenting with only an atypical symptom, without the typical history of regurgitation, which is the usual reason to raise the index of suspicion for GERD. This is a clear teaching of silent GERD, and based on the reference, known GERD treatments would be expected to be effective for treating silent GERD. When

taken with the case report including the reported child's frequent night disturbances, the references in combination would have motivated one of ordinary skill in the art at the time of the invention to apply the method of treating GERD (taught by Amin) to the patient subpopulation of individuals with silent GERD, having only the symptom of sleep disturbances, that are also without a typical history of regurgitation and other traditional reflux symptoms. This silent GERD with sleep disturbance is a specific condition specie within the generic method of treating gastric acid related diseases, taught by Amin. Based on the recognition of this condition from the teaching of Carr, it would have rendered obvious the application of the generic method to this condition specie. Therefore the rejection is maintained.

4. The double patenting rejection is maintained for the reasons of record:

Claims 20-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-6 of copending Application No. 11/912954 in view of Amin et al. (WO 99/55706; 1999; IDS 5/2/2006 reference) and Carr et al. ("Case Report: Severe non-obstructive sleep disturbance as an initial presentation of gastroesophageal reflux disease"; 1999: International Journal of Pediatric Otorhinolaryngology' 51: 115-120; IDS 5/1/2007reference, Cite No. C).

Conclusion

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1628

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642